UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,125	10/21/2003	Pierpaolo Correale	126442-100008-US	5287

21890 7590 10/02/2007

PROSKAUER ROSE LLP
PATENT DEPARTMENT
1585 BROADWAY
NEW YORK, NY 10036-8299

EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,125	CORREALE ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-7,9-17 and 19-28* is/are pending in the application.

4a) Of the above claim(s) *9-17 and 20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 4, 5, 7, 19* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This FINAL action is in response to the paper filed on 6/26/2007.

Status of Claims

Claims 2, 4-7 and 19 are under consideration. Claims 1, 3, 8, and 18 are cancelled. Claims 9-17 and 20-28 are withdrawn.

Rejections Withdrawn

All rejections not present in this office action are withdrawn because Applicants amended the claims to state that the isolated peptide is selected from the group "consisting of" instead as previously claimed that the peptide "comprises" amino acid sequences. Also, Applicants no longer claim SEQ ID NO:1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 does not satisfy the written description requirement with regard to the functional variants of SEQ ID NOs:2, 3, 4 or 5, because there is an infinite number of such variants that do not necessary resemble SEQ ID NOs: 2-5. Therefore, the

undisclosed variants structure do not correspond with the necessary function of the peptide.

Claim 4 does not satisfy the written description because the structure of the "helper epitope" is not provided, and thus the structure of the epitope does not correspond with its function.

Claim 19 is included in this rejection because Applicants claim a kit composed of the PTH-rP peptide and instructions for use. However, the instructions for use do not cure the lack of adequate written description of claim 2.

Applicants responded that functional variants are adequately described in the specification paragraphs [0024-0027] and that such guidance is provided in these paragraphs.

Examiner reviewed paragraphs [0024-0027] and the only functional variants that are specially claimed are SEQ ID NOs:2-5. Therefore, the rejection stands since no other variants are discussed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 5, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardella et al., WO200023594.

Gardella et al. teach PTHrP peptides and SEQ ID NO:8 on page 26, lines 25-26 that is identical with the instant SEQ ID NO:2.

The instant SEQ ID NOs:3-5 are included in this rejection because they are functional variants of SEQ ID NO:2.

Claim 5 is included in this rejection because the peptide can consists of two or more SEQ ID NO:2 in a isolated complex, for example.

Claim 19 is included in this rejection because SEQ ID NOs: 2-5 are PTHrP and the instructions in a kit are not patentable subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardella et al. in view of Yoneda et al. U.S. 5,993,817 .

Yoneda et al. teach anti-PTH-rP that can be prepared in a variety of ways; where a suitable immunogen, such as PTH-rP or its subunit is administered to a vertebrate-capable of an immune response to the immunogen; where particularly preferred subunits of PTH-rP include those in the N-terminal region, in particular positions 1-34; and where the PTH-rP or subunit used as immunogen should include **epitopes**

characteristic of the particular species PTH-rP for which antibodies are described. See column 6, lines 1-11.

Therefore, it would have been obvious to one of an ordinary skill in the art at the time the invention was made to design a peptide of SEQ ID NOs:2-5 as taught by Bagnoli et al. which comprises a helper epitope as taught by Yoneda et al. because such designs are known in the art and there is a great predictability that such design will work for its intended purposes.

Objection to claims

Claim 6 is objected to because it depends from rejected claim 5.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-273-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER